June 1, 2006

Standard Operating Procedure
for
Performance Verification of the Yamato Drying Oven
(Mechanical Convection Oven)

SOP Number: QC-23-00

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Performance Verification of the Yamato Drying Oven
(Mechanical Convection Oven)

SOP Number: QC-23-00

Date Revised: 06-01-06

Initiated By: _____ Date: ___/___/___

Print Name: _____

Technical Review: _____ Date: ___/___/___

Print Name: _____
Technical Staff

QA Review: _____ Date: ___/___/___

Print Name: _____
QA Officer

Approved By: _____Date: ___/___/___

Print Name: _____
Branch Chief

Effective Date: ___/___/___

Controlled Copy No.: _____

Withdrawn By: _____ Date: ___/___/___

TABLE OF CONTENTS

1.0 SCOPE AND APPLICATION:

1.1 This protocol describes procedures for the verification of performance for the Yamato drying oven.

2.0 DEFINITIONS:

2.1 NIST = National Institute of Standards and Technology

3.0 HEALTH AND SAFETY:

3.1 When operating ovens, always observe the following safety precautions:
- Wear insulated gloves
- Use tongs
- Never stand in front of an open operating oven
- Use safety glasses

3.2 As a safety precaution, disconnect the power cord from the power source when inspecting or maintaining this unit. Prior to each use, perform inspection and maintenance procedures. To clean, wipe the unit with a soft cloth dampened with deionized water. Using tap water on this unit may attract dirt.

4.0 CAUTIONS:

4.1 Since drying ovens use high temperatures, it is necessary to exercise extreme caution around the device. High-temperature surfaces can be encountered even when the device is not in a sterilizing cycle.

4.2 Be cautious when opening and closing the door.

4.3 Do not place items directly on bottom plate of the oven. This will disturb the performance and furthermore, the internal temperature and will cause malfunctions. Be sure to utilize the shelves provided.

5.0 INTERFERENCES:

5.1 Follow storage conditions for Dry Heat and Biological Indicator Spore Strips as specified in section 9.0.

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS:

7.1 Drying oven located in B209, Yamato Mechanical Convection Oven, Model DKN810, Serial No. DKN811B4600129

7.2 Raven Biological Laboratories Dry Heat Indicator Labels

7.3 Drytrol Sterilization Monitors for Dry Heat

7.4 Raven Biological Laboratories Spore Strips with 10^6 spores of *Bacillus atrophaeus* (ATCC #9372)

7.5 Raven Biological Laboratories Soybean Casein Digest Broth

7.6 Incubator with temperature at 30E∀1EC

7.7 Certified Dickson FT121 Digital Logger, S/N 04191535

8.0 INSTRUMENT OR METHOD CALIBRATION:

8.1 Digital Display must be annually certified through the manufacturing company.

9.0 SAMPLE HANDLING AND STORAGE:

9.1 Soybean Casein Digest Broth must be stored according to manufacturer's specifications to insure shelf life. Care must be taken to insure that the box of broth tubes is unpacked immediately upon arrival and placed in the refrigerator.

9.2 Dry Heat Indicator Labels are to be stored according to manufacturer's specifications. Take care to protect from moisture and excessive humidity.

9.3 Biological Indicator Spore Strips are to be stored according to manufacturer's specifications. Take care to protect from sterilizing agents, avoid sunlight, and all other forms of UV light. DO NOT REFRIGERATE.

10.0 PROCEDURE AND ANALYSIS:

10.1 Summary:

10.1.1 Drying Oven performance will be verified by examining the spore strips, Drytrol sterilization monitors, and Dry Heat Indicator Labels. Specifically, the indicator labels and Drytrol sterilization monitors will be used with every sterilization run. The indicator labels, Drytrol sterilization monitors, and spore strips will be used for the monthly performance verifications described in Section 10.2.

Table 10.1.1 Performance Verification Elements for the Drying Oven

Room and Unit ID	Dry Heat Indicator Labels		Drytrol Sterilization Monitors		Spore Strips	
	R*	M*	R*	M*	R*	M*
B209 Drying Oven	✓	✓	✓	✓	N/A	✓

* R = Routine (per load) M = Monthly N/A = Not Applicable

10.2 Performance Verification Procedures for the Drying Oven.

10.2.1 Entering/Verifying Settings for Digital Temperature Logger (To be performed with each cycle)

10.2.1.1 Press set button. It will display a warning message, press set again. **"Set time/Div"** is displayed. At this point logger will reset.

10.2.1.2 At the **"Set time/Div"** select the **1 hour/div**. Press set again.

10.2.1.3 At the **"Set V Scale"** select the **0 to 250**. Press set again.

10.2.1.4 At the **"Set F or C"** select **Celsius**. Press set again.

10.2.1.5 At the **"Set Date"** enter in date using the arrow keys. Press set again.

10.2.1.6 At the **"Set Time"** enter in time using the arrow keys. Press set again.

10.2.2 Entering/Verifying Settings for Drying Oven

10.2.2.1 Press timer button. **"AStp"** (auto-stop) will be displayed. Press enter.

10.2.2.2 **"SV"** (set temperature) will be displayed. Use arrow keys to set to 180. Press enter.

10.2.2.3 **"Tim"** (set time) will be displayed. Use arrow keys to set to 2.00. Press Start/Stop till oven clicks on.

10.2.3 Routine Runs (Per Load)

10.2.3.1 Dry Heat Indicator Labels. Place one label on each item to be sterilized. Do not attach to glass. Indicator label will turn black when exposed to heat. NOTE: Dry Heat Indicator Labels are used to visually verify that items have been through a

drying cycle. Labels DO NOT indicate sterilization.

10.2.3.2 Drytrol Sterilization Monitors. Randomly place two indicators per shelf being utilized. Place inside glassware. Sterilization occurs when the pellet inside changes color from blue to pink

10.2.3.3 Record results on the appropriate forms. (See 16.1) Results of the Dry Heat Indicator labels are observed only; a deviation is documented if any of these indicators fail to turn black. Those items with labels that did not turn black must be re-sterilized.

10.2.4 Procedures for Monthly Performance Verification for the Drying Oven.

10.2.4.1 Follow section 10.2.3.1

10.2.4.2 Place three Drytrol sterilization monitors on each shelf being used. Place one towards the front, one in the middle, and one towards the back inside of various glassware. Sterilization occurs when the pellet inside changes color from blue to pink.

10.2.4.3 In addition, use spore strips:

10.2.4.3.1 Place two strips in glass Petri dishes between two pieces of filter paper. Place another strip in a 100 mL flask, and one more in a 1000 mL screw top bottle, both tops are wrapped with foil. Randomly place the glassware with spore strips throughout the oven.

10.2.4.3.2 Remove strips and aseptically place each one into a separate vial of Raven Biological Laboratories Soybean Casein Digest Broth. Place an untreated spore strip into a separate vial of broth to serve as a positive control. Place vials into a 30°C ± 2°C incubator for up to 7 days.

10.2.4.3.3 Observe daily for growth. If turbidity is present in the broth, proper sterilization was not achieved. Confirm the growth as the test organism by Gram stain (Gram positive large rods). If growth of the test organism is confirmed, then that sterilization cycle failed and all glassware from that cycle must be resterilized. Refer to table 14.1.

10.2.4.3.4 Refer to table 14.1 for interpretation of results. Record results on the appropriate forms. (See 16.2)

11.0 DATA ANALYSIS/CALCULATIONS: See table 14.1 for interpretation of results.

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Data will be recorded promptly, legibly, and in indelible ink. Information on daily drying oven runs will be recorded on the Routine Sterilization Record Information Form (see 16.1). Information on monthly QC drying oven runs will be recorded on the Monthly Sterilization Record Information Form (see 16.2). Completed forms are archived in notebooks kept in secured file cabinets in file room D217. Only authorized personnel have access to the secured files. Archived data is subject to OPP=s official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 Performance verification of the Yamato drying oven is conducted with each load as described in sections 10.2.3, and is conducted monthly as described in sections 10.2.4. See table 10.1. for a summary of performance verification requirements.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Refer to Table 14.1 for interpretation of results and appropriate corrective actions for nonconformance.

Table 14.1 Interpretation of Results

Drytrol	Spore Strips	Interpretation of Results and *Corrective Action* for the Yamato Drying Oven
Pass	**Pass**	**Indicates all parameters have passed.**
Fail	**Fail**	**Indicates that oven did not reach sterilization temperature for the required time. Repeat monthly performance verification. If still nonconformance, tag out of service and call for service.**
Fail	**Pass**	**Indicates that oven has sterilized contents. Drytrol failed. No corrective action needed.**
Pass	**Fail**	**Indicates that oven has reached sterilization temperature but has not sterilized contents. Repeat monthly performance verification.**
Fail	**N/A**	**Indicates that oven did not reach sterilizing temperature. Repeat daily cycle.**

15.0 REFERENCES:

15.1 Instruction Manual for Yamato Mechanical Convection Oven DKN-810, Yamato Scientific America, Inc. Ver.3 December 27, 2003.

15.2 Eaton, A.D., Clesceri, L.S., Greenberg, A.E. eds. 1995. Standard Methods for the Examination of Water and Wastewater, 19th Edition. American Public Health Association, American Water Works Association, Water Environment Federation.

16.0 FORMS AND DATA SHEETS:

16.1 Routine Sterilization Record Log Form for Drying Oven.

16.2 Monthly Sterilization Record Log Form for Drying Oven.

Routine Sterilization Record Log Form for Drying Oven

OPP Microbiology Laboratory

Drytrol Sterilization Monitor Results[1]	Items Processed	Sterilization No.[2]	Temp[3]	Init.

1 Record the results for each of the Drytrol Sterilization Monitors as "P" for pass or "F" for fail. (i.e, for 6 monitors, enter 6 P's)

2 The Sterilization No. indicates the date as well as the unit location and the run number. (S-MMDDYY-9XX, S=sterilization, 9=room 209, XX=run number)

3 Record highest recorded temperature from the logger.

Monthly Sterilization Record Log Form for Drying Oven

OPP Microbiology Laboratory

Init.	Sterilization Run No.[1]	Drytrol Sterilization Monitor Results[2]	Soybean Casein Digest Broth Control No.	Temp[3]	Date/ Init	Spore Strip Results[4]				Spore Strip Control No.
						1	2	3	4	

1. The Sterilization No. indicates the date as well as the unit location and the run number. (S-MMDDYY-9XX, S=sterilization, 9=room 209, XX=run number)
2. Record the results for each of the Drytrol Sterilization Monitors as “P” for pass or “F” for fail. (i.e., for 6 monitors, enter 6 P’s)
3. Record the highest recorded temperature from the logger.
4. Record positive results of the spore strips for up to 7 days as “G” for Growth (Fail) and on the 7th day if no growth record negative results as “N” for No Growth (Pass).